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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,361	05/24/2000	Tamara Macs	4409US	4901

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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	PAPER NUMBER
1656	11

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/578,361	MAES ET AL.	
	Examiner	Art Unit	
	Teresa E Strzelecka	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 15, 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Office action is in response to an amendment filed on October 15, 2001.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is drawn to a method of claim 1 "...wherein the organism is a cell line...". According to the "Webster's II New Riverside University Dictionary" organism is defined as "A plant or animal or microscopic organism", which encompasses both structural and functional diversity not provided by a cell line.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 7, 9-11, 19, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dellaporta (U.S. Patent No. 6,013,486) and Koes et al. (PNAS USA, Vol. 92, pp. 8149-8153, 1995).

A) Dellaporta teaches a method of screening for gene insertion mutants in a population of organisms by preparing a library of insertion elements and insertion element flanking

sequences, amplifying the insertion elements flanking sequences using primers derived from the flanking sequences, and either fixing the amplified products to a solid support to serve as targets for amplification or the labeling the amplified products to be used as probes. The organism can be a plant. The amplification of insertion element flanking sequences can be achieved by iPCR (inverse PCR), which comprises digesting the insertion element mutant library with a restriction enzyme, self-ligation of fragments to form circles and amplifying the insertion element flanking sequences using primers based on the terminal part of the insertion element. The digesting enzyme could be BfaI or MseI (col. 2, lines 1-15, 57-67; col. 3, lines 48-67; col. 4, lines 1-8, 39-46; col. 5, lines 15-34; col. 11, lines 43-67; col. 12, lines 1-39; col. 13, lines 58-67; col. 14, lines 1-5; col. 15, lines 6-14, 47-57; col. 28, lines 17-19).

Pools containing DNA from different combinations of individuals, designed in such a way that sequences representing single members of a population can be identified without the need to analyze each member individually. For example , pools can be distributed into a 2x2 grid, comprising rows and columns. (col. 3, lines 58-65; col. 15, lines 58-67).

B) Dellaporta teaches forming pools of DNA but does not teach 30 DNA samples from 100 plants each, wherein the DNA from 100 plants is distributed into a 3D array of 10 blocks, 10 rows and 10 columns.

C) Koes et al. describe a method of preparing an insertion element mutant library of transposable elements dTph1 in petunia plants. They describe pooling plant material from three sets of 1,000 plants each in patterns of blocks, rows and columns, e.g. 10 blocks, 10 rows, 12 columns (page 8150, col. 2, par. 4,5; Fig. 2, 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the DNA pooling method of Koes et al. in the insertion element library screening method of Dellaporta. The motivation to do so, expressly provided by Koes et al., would have been that three-dimensional was less laborious (single round of screening), less liable to detect false positives and identified single plants directly.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dellaporta and Koes et al. as applied to claims 1-3 above, and further in view of Souer et al. (The Plant Journal, Vol. 7, pp. 677-685, 1995).

A) Claim 4 is drawn to reamplifying at least one amplifiable genomic fragment with at least one primer based on a sequence of a nucleic acid insertion element.

B) Neither Dellaporta nor Koes et al. teach reamplifying at least one amplifiable genomic fragment with at least one primer based on a sequence of a nucleic acid insertion element.

C) Souer et al. teach a method of isolating gene insertion mutants in petunia plants based on the amplification of insertion element dTph1 flanking sequences using a combination of iPCR and differential screening of amplification products (page 678, col. 1, par. 1).

Amplification by iPCR comprises:

i) digesting genomic DNA using a restriction enzyme,

ii) self-ligation of the digested fragments to form circles, and

iii) amplification with an insertion element specific primer (page 678, col. 2, last paragraph; Fig. 2).

Amplification yield can be improved by using re-amplification with nested primers complementary to the insertion element (page 680, col. 1, par. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used re-amplification of Souer et al. in the combined method of Dellaporta and Koes et al. The motivation to do so, expressly provided by Souer et al, would have been that re-amplification improved the yield of amplification of dTph1 flanking sequences.

5. Claims 5, 6, 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dellaporta and Koes et al. as applied to claim 1 above, and further in view of Vos et al. (Nucleic Acids Res., Vol. 23, pp. 4407-4414, 1995).

A) Claims 5 and 6 are drawn to "transposon display amplification" comprising:

i) digesting nucleic acid sequences from the gene insertion mutant library with two restriction enzymes, one cutting a 6 base pair (bp) site and the other a 4 bp site,

ii) ligating a biotinylated adaptor to the hexacutter site and a second adaptor to the tetracutter site,

iii) selecting biotinylated restriction fragments using streptavidin beads,

iv) amplifying insertion element flanking sequences using primer based on the biotinylated adaptor and insertion element sequence and a primer complementary to the second adaptor,

v) re-amplifying insertion element flanking sequences using nested primer based on the insertion element and a primer complementary to the second adaptor.

Claim 8 is drawn to nucleic acid sequences selected from the group consisting of genomic DNA and cDNA, and claim 12 to using a restriction enzyme from the group consisting of MseI and MunI.

B) Neither Dellaporta nor Koes et al. teach amplification by transposon display amplification.

C) Vos et al. teach a DNA fingerprinting technique (transposon display amplification) comprising:

i) digesting DNA with two restriction enzymes, recognizing a 6 bp and 4 bp sites, e.g. EcorI and MseI,

ii) ligating a radiolabelled adaptor to the hexacutter site and a second adaptor to the MseI site,

iii) amplification of the restriction fragments using primers complementary to the adaptors and restriction site sequences.

The fragments could be subjected to a second round of amplification using modified primers (Abstract; page 1408). The amplified fragments can be selected by using a biotinylated adapter for the hexacutter site and separated from the rest of the fragments with streptavidin beads (page 4413, col. 2, par. 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the DNA amplification method of Vos et al. with the library of gene insertion mutants of Dellaporta and Koes et al. The motivation to do so, expressly provided by Vos et al., would have been that amplification and isolation of DNA fragments was achieved without the prior knowledge of their sequences.

6. Claims 13-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dellaporta and Koes et al. as applied to claims 1 and 19 above.

A) Claims 13-17 are drawn to a kit for performing the method of claim 1, comprising DNA samples of an insertion element mutant library, a set of amplified insertion element flanking sequences, which may be fixed to a solid support, be in soluble or dried state or be labeled

with fluorescein. Claim 21 is drawn to a kit for performing the method of claim 19, the kit comprising DNA samples of an insertion element mutant library.

B) The reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time of the invention.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have packaged the insertion element mutant library and amplified insertion element flanking sequences into a kit for the expected benefits of convenience and cost-effectiveness for practitioners in the art wishing to perform screening for insertion mutants.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
December 13, 2001

Kenneth R. Horlick, Ph.D.
KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1600
12/17/01